

Terrestrial Animal Health Standards Commission Report September 2015
USA Comments – indicated in blue font

DRAFT CHAPTER 8.X.

**INFECTION WITH MYCOBACTERIUM
TUBERCULOSIS COMPLEX**

Article 8.X.1.

General provisions

The recommendations in this chapter are intended to manage the human and animal health risks associated with *infection* of animals with a member of the *Mycobacterium tuberculosis* (*M. tuberculosis*) complex.

For the purposes of this chapter, *M. tuberculosis* complex comprises *M. bovis*, *M. caprae* and *M. tuberculosis*, but excludes vaccine strains.

Many different domestic and wild animal species belonging to diverse mammalian taxa are known to be susceptible to *infection* with *M. tuberculosis* complex. Their epidemiological significance depends on the degree of susceptibility, the husbandry system, the density, spatial distribution and ecology of populations as well as the pathogenesis and transmission pathways. In some geographical regions, certain *wild animal* species can act as reservoirs.

For the purposes of this chapter, 'animals' means domestic and *captive wild* animal populations of the following categories:

- 1) Bovids: this term means cattle (*Bos taurus*, *B. indicus*, *B. frontalis*, *B. javanicus* and *B. grunniens*), water buffalo (*Bubalus bubalis*), and bison (*Bison bison* and *B. bonasus*).
- 2) Cervids: this term means red deer (*Cervus elaphus elaphus*), wapiti/elk (*C. elaphus canadensis*), sika (*C. nippon*), samba (*C. unicolor unicolor*), rusa (*C. timorensis*), roe deer (*Capreolus capreolus*), fallow deer (*Dama dama*), white-tailed, black-tailed and mule deer (*Odocoileus* spp) and reindeer/caribou (*Rangifer tarandus*).
- 3) Goats (*Capra hircus*).
- 4) New World Camelids (under study).

The chapter deals not only with the occurrence of clinical signs caused by *infection* with *M. tuberculosis* complex, but also with the presence of *infection* with *M. tuberculosis* complex in the absence of clinical signs.

For the purposes of the *Terrestrial Code*, the following defines the occurrence of *infection* with *M. tuberculosis* complex:

- A member of *M. tuberculosis* complex has been identified in a sample from an animal or a product derived from that animal;

OR

- positive results to a diagnostic test have been obtained and there is an epidemiological link to a case of *infection* with *M. tuberculosis* complex or there is other reason to suspect *infection* with *M. tuberculosis* complex.

When authorising import or transit of *commodities* listed in this chapter, with the exception of those listed in Article 8.X.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the *M. tuberculosis* complex *infection* status of the animal population of the country, *zone* or *herd* of origin.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 8.X.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *M. tuberculosis* complex-related conditions, regardless of the *M. tuberculosis* complex *infection* status of the animal populations of the country, *zone* or *herd* of origin:

- 1) *fresh meat* and *meat products* originating from animals that have been subjected to ante- and post-mortem inspection as described in Chapter 6.2.;
- 2) cured hides, skins and trophies;
- 3) gelatine, collagen, tallow and *meat-and-bone meal*.

Article 8.X.3.

Country or zone historically free from infection with *M. tuberculosis* complex in specified animal categories

A country or *zone* may be considered historically free from *infection* with *M. tuberculosis* complex in specified animal categories when the conditions of point 1a) of Article 1.4.6 have been met for the relevant animal categories.

Article 8.X.4.

Country or zone free from infection with *M. tuberculosis* complex in bovids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:
 - a) *infection* in animals is a *notifiable disease* in the entire country;
 - b) regular testing of all *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8 % of the *herds* representing at least 99.9 % of the bovids in the country or *zone*;
 - c) a *surveillance* programme is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspection as described in Chapter 6.2.;
 - d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in bovids;
 - e) bovids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.10. and 8.X.12.;
- 2) To maintain the status as free from *infection* with *M. tuberculosis* complex in bovids, a country or *zone* should satisfy the following requirements:
 - a) the requirements in points 1a), 1c), 1d) and 1e) are met;
 - b) a *surveillance* programme based on regular testing of bovids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;
 - c) once the *surveillance* programme described in point b) has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8 % of the *herds* representing 99.9 % of the bovids in the country or *zone* for ~~two~~ five consecutive years, *surveillance* may be maintained through ante- and post-mortem inspection as described in Chapter 6.2.;

Rationale: Previously this requirement was for 5 years. The United States recommends maintaining the 5-consecutive year testing requirement before transitioning to an all

slaughter surveillance program of case finding. Further, this is a time when “insurance testing” of previously infected herds (and which have been released from quarantine) should be done. It is a critical time period during which one should look for secondary infection from any skin test negative animals remaining in the herd after a test-and-remove protocol.

- 3) The country or *zone* status of free from *infection* with *M. tuberculosis* complex in bovids is not affected by the occurrence of *infection* with *M. tuberculosis* complex in other animal categories or *feral* or *wild animals* provided that measures have been implemented to ~~prevent~~ mitigate transmission of *infection* with *M. tuberculosis* complex to bovids.

Rationale: The United States suggests changing “prevent” to “mitigate” because the word “prevent” implies elimination of risk or zero risk. Also, this would be inconsistent with the definition of Historical Freedom which does not allow for the presence of disease in feral or wild animals, 8.X.3.

Article 8.X.5.

Country or zone free from infection with *M. tuberculosis* complex in cervids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:
 - a) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;
 - b) regular testing of all cervid *herds* has been in place for at least three years and for the past three years this testing has demonstrated that *infection* with *M. tuberculosis* complex was not present in at least 99.8 % of the *herds* representing at least 99.9 % of the cervids in the country or *zone*;
 - c) a *surveillance* programme is in place to detect *infection* with *M. tuberculosis* complex in the country or *zone* through ante- and post-mortem inspection as described in Chapter 6.2.;
 - d) regulatory measures have been implemented for the early detection of *infection* with *M. tuberculosis* complex in cervids;
 - e) cervids and their germplasm introduced into the country or *zone* comply with the recommendations in Articles 8.X.7., 8.X.11. and 8.X.12.
- 2) To maintain the status as free from *infection* with *M. tuberculosis* complex in cervids, a country or *zone* should satisfy the following requirements:
 - a) the requirements in points 1a), 1c), 1d) and 1e) are met;
 - b) a *surveillance* programme based on regular testing of cervids is in place in the country or *zone* to detect *infection* with *M. tuberculosis* complex in accordance with Article 1.4.4.;
 - c) once the *surveillance* programme described in point b) has demonstrated that *infection* with *M. tuberculosis* complex has not been present in at least 99.8 % of the *herds* representing 99.9 % of the cervids in the country or *zone* for ~~two~~ five consecutive years, *surveillance* may be maintained through ante- and post-mortem inspection as described in Chapter 6.2.;

Rationale: Previously this requirement was for 5 years. The United States recommends maintaining the 5-consecutive year testing requirement before transitioning to an all slaughter surveillance program of case finding. Further, this is a time when “insurance testing” of previously infected herds (and which have been released from quarantine) should be done. It is a critical time period during which one should look for secondary infection from any skin test negative animals remaining in the herd after a test-and-remove protocol.

- 3) The country or *zone* status free from *infection* with *M. tuberculosis* complex in cervids is not affected by the occurrence of *infection* with *M. tuberculosis* complex in other animal categories or *feral* or *wild animals* provided that measures have been implemented to ~~prevent~~ mitigate transmission of *infection* with *M. tuberculosis* complex to cervids.

Rationale: The United States suggests changing “prevent” to “mitigate” because the word “prevent” implies elimination of risk or zero risk. Also, this would be inconsistent with the definition of Historical Freedom which does not allow for the presence of disease in feral or wild animals, 8.X.3.

Article 8.X.6.

Herd free from infection with *M. tuberculosis* complex in bovids or cervids

- 1) To qualify as free from *infection* with *M. tuberculosis* complex, a *herd* of bovids or cervids should satisfy the following requirements:
 - a) the *herd* is in a country or *zone* free from *infection* with *M. tuberculosis* complex in bovids or in cervids and is certified free by the *Veterinary Authority*;

OR

 - b) the *herd* meets the following conditions:
 - i) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;
 - ii) no evidence of *infection* with *M. tuberculosis* complex has been detected in the *herd* for at least the past 12 months;
 - iii) bovids or cervids in the *herd* have shown no clinical signs of *infection* with *M. tuberculosis* complex or lesions at ante- or post-mortem inspection for at least the past 12 months;
 - iv) two tests have been performed with negative results at a minimum interval of six months on all bovids or cervids over six weeks of age present in the *herd* at the time of testing. The first test was performed at least six months after the removal of the last case;
 - v) bovids or cervids and their germplasm introduced into the *herd* comply with Articles 8.X.7., 8.X.10., 8.X.11. and 8.X.12.;
 - vi) for at least the past 12 months, there has been no evidence of *infection* with *M. tuberculosis* complex in other *herds* of the same *establishments* or measures have been implemented to prevent any transmission of *infection* with *M. tuberculosis* complex from these other *herds*;
- 2) to maintain the free status, either:
 - a) the requirements in point 1a) are met;

OR

 - b) the requirements in point 1b i) to iii), v) and vi) are met and bovids or cervids in the *herd*:
 - i) showed a negative result to an annual test to ensure the continuing absence of *infection* with *M. tuberculosis* complex;

OR

 - ii) showed a negative result to a test every two years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 1 % of all *herds* in the country or *zone* during the past two years;

OR

- iii) showed a negative result to a test every three years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 0.2 % of all *herds* in the country or *zone* during the past four years;

OR

- iv) showed a negative result to a test every four years to ensure the continuing absence of *infection* with *M. tuberculosis* complex if it has been confirmed that the annual percentage of *herds* infected with *M. tuberculosis* complex is not more than 0.1% of all *herds* in the country or *zone* during the past six years;

Article 8.X.7.

Recommendations for the importation of bovids and cervids for breeding or rearing

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the bovids and cervids:

- 1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;
- 2)
 - a) originate from a *herd* free from *infection* with *M. tuberculosis* complex that is in a country or *zone* free from *infection* with *M. tuberculosis* complex; or
 - b) originate from a *herd* free from *infection* with *M. tuberculosis* complex and have been tested for *infection* with *M. tuberculosis* complex with negative results within 30 days prior to shipment; or
 - c) have been isolated for at least 90 days prior to shipment including protection from contact with *animal* reservoirs of *M. tuberculosis* complex and all isolated animals showed negative results to at least two consecutive tests carried out at a six-month interval, with the second test performed within 30 days prior to shipment.

Article 8.X.8.

Recommendations for the importation of goats for breeding or rearing

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

- 1) *infection* with *M. tuberculosis* complex in animals is a *notifiable disease* in the entire country;
- 2) the goats showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;
- 3) the goats were kept in *herds* in which no case of *infection* with *M. tuberculosis* complex has been detected for the past three years.

Article 8.X.9.

Recommendations for the importation of bovids and cervids for slaughter

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that bovids and cervids:

- 1) showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of shipment;
- 2)
 - a) originate from a country, *zone* or *herd* free from *infection* with *M. tuberculosis* complex; or
 - b) are not being culled as part of an eradication programme against *infection* with *M. tuberculosis* complex and were tested for *infection* with *M. tuberculosis* complex with negative results within 30 days prior to shipment.

Article 8.X.10.

Recommendations for the importation of semen of bovids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;
- 2) the donor males either;
 - a) were kept in an *artificial insemination centre* complying with the provisions of Chapter 4.5.; or
 - b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to tests carried out annually and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.;

Article 8.X.11.

Recommendations for the importation of semen of cervids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor males showed no clinical signs of *infection* with *M. tuberculosis* complex on the day of collection of the semen;
- 2) the donor males either;
 - a) were kept in a *herd* free from *infection* with *M. tuberculosis* complex in a country or zone free from *infection* with *M. tuberculosis* complex and which only accepts cervids from free herds in a free country, or zone; or
 - b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex and showed negative results to tests carried out annually and the semen was collected, processed and stored in conformity with the provisions of Articles 4.5.3. to 4.5.5. and Articles 4.6.5. to 4.6.7.

Article 8.X.12.

Recommendations for the importation of embryos of bovids and cervids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females either;
 - a) originated from a *herd* free from *infection* with *M. tuberculosis* complex in a country or zone free from *infection* with *M. tuberculosis* complex; or
 - b) were kept in a *herd* free from *infection* with *M. tuberculosis* complex, and were subjected to a test for *infection* with *M. tuberculosis* complex with negative results during an isolation period of 30 days in the *establishment* of origin prior to collection;
- 2) the embryos were collected, processed and stored in accordance with the relevant provisions of Chapters 4.7. to 4.9.

Article 8.X.13.

Recommendations for the importation of milk and milk products of bovids

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the *milk* or *milk products*:

- 1) have been derived from bovids in a *herd* free from *infection* with *M. tuberculosis* complex; or

- 2) were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

Article 8.X.14.

Recommendations for the importation of milk and milk products of goats

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that:

- 1) *infection with M. tuberculosis complex* in animals is a *notifiable disease* in the entire country and the *milk* or *milk products* have been derived from goats kept in *herds* in which no *case of infection with M. tuberculosis complex* has been detected for the past three years;

OR

- 2) the *milk* or *milk products* were subjected to pasteurisation or any combination of control measures with equivalent performance as described in the Codex Alimentarius Code of Hygienic Practice for Milk and Milk Products.

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